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Physiological Evaluation of First Responder Mask

by Ronald A. Weiss and Judith Pasternak-Silva

ARL-TR-3060 September 2003

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14. ABSTRACT
The First Responder Mask (FIRM) was developed for domestic preparedness/counterterrorism personnel (e.g., firefighters, police, medical support, search and rescue, security, investigators) to provide at least 12 hr of continuous protection against chemical/biological exposure when a terrorist incident or chemical emergency required their participation. It is a powered air-purifying respirator with adjustable hood, nosecup, and one-size-fits-all neck dam configuration. This physiological evaluation of the FIRM tested its suitability for human use prior to submission to the National Institute for Occupational Safety and Health for certification. The mask provided adequate filtered ventilation for sustained heavy workloads. Oxygen and carbon dioxide concentration within the FIRM remained at or near ambient levels during rest and exercise with the blower on. With blower off or loose nosecup, the oxygen concentration fell to ~20.2% and carbon dioxide rose an average of 0.29% over the 20-min test period. This would allow ample time for anyone in a contaminated area to reach safety when a blower fails or the battery is discharged. Visual acuity, color acuity, depth perception, field of view, and contrast sensitivity wearing the mask were essentially the same as the unmasked control values in the same subject. A commercial soda/water bottle can be connected to the FIRM's drink tube fitting.

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respirator, first responder mask, physiological evaluation, respirator, visual tests, human testing, drink tube, one-size-fits-all neck dam, counter-terrorism, domestic preparedness, blower, chemical emergency, PAPR, soda bottle connection, oxygen, carbon dioxide

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1. Introduction

The First Responder Mask (FIRM) was developed for domestic preparedness and counterterrorism personnel (e.g, firefighters, police, medical support, search and rescue, security, investigators) to provide at least 12 hr of continuous protection against chemical/biological exposure when a terrorist incident or chemical emergency required their participation. Personnel responding to such an incident are subject to extended periods of physical exertion and psychological and environmental stress that is exacerbated by the confining presence of a protective mask and clothing.

Participants from 31 responder groups representing various federal, state, county, and city government agencies convened in February 1996 to identify their requirements for such a mask. The requirements established were as follows:

- Provide a high-protection fit factor of at least 10,000 for the chemical and biological exposure levels expected from a terrorist or emergency incident.
- Provide a minimum of 12 hr of protection at high work levels in a contaminated area.
- Be easily donned, regardless of previous mask use experience.
- Have a one-size-fits-all configuration to accommodate personnel with different facial structure, hair length, beards, age, gender, etc., and those who use corrective lenses.
- Permit a range of mission-essential tasks that vary in type of task, time involved, and levels of physical exertion.
- Permit interfacing with all types of equipment used by various responder groups (such as helmets, communication systems, protective clothing, optical devices, and group-specific equipment).
- Provide wear comfort and minimal hindrance in performing tasks when worn for extended periods.
- Provide the capability for drinking from bottled fluid sources (i.e., water, soda, etc.).
- Impart a high degree of self-confidence in the users when working in a contaminated area so they can concentrate on performing their mission rather than worrying about their own safety.
- Be certified by the National Institute of Occupational Safety and Health (NIOSH) for civilian occupational use.

In response to these requirements, DEA Research and Development, Inc., Jerusalem, Israel, developed the FIRM under the joint sponsorship of the Department of Defense Office of Special Technology and the Israeli Ministry of Defense.

The Protection factor testing of the FIRM was conducted at the Israeli Institute of Biological Research, and the results were presented at the International Symposium on Protection Against Chemical and Biological Warfare Agents in Stockholm, Sweden (*1*). Results of field trials with this respirator, conducted in association with several participating user groups, have been reported by the U.S. Army Research Laboratory (ARL), Aberdeen Proving Ground, MD (*2*).

This report covers a physiological evaluation conducted by ARL at Aberdeen Proving Ground, MD, to determine the FIRM's suitability for human use, prior to being submitted to NIOSH for certification. The evaluation also examined a preliminary finding by NIOSH, based on their breathing simulator, that elevated carbon dioxide (CO_2) levels (i.e., up to 7% concentration within a 20-min period) were apparent inside the hood if the blower battery failed (*3*).

2. Mask Description

The FIRM (Figures 1 and 2) is a uniquely designed, powered air-purifying respirator. Instead of using the standard, close-fitting, peripheral facial seal to provide eye/respiratory protection, the FIRM uses a one-size-fits-all elastomeric neck dam configuration. As an integral part of the adjustable hood, this neck dam configuration provides protection and a comfortable fit over a wide range of head and neck sizes, eliminating the need for multiple mask sizes. The one-size-fits-all FIRM consists of a rigid polycarbonate face piece bonded to an adjustable, agent-resistant hood, exhalation and pressure relief valve assemblies, drink tube, internal nosecup, neck dam, single-speed blower with two filter canisters, and hose connecting the blower to the face piece. The weight of the mask/hose portion of the FIRM is 825 g, and the weight of the blower assembly (with battery and two filter cartridges) is 1325 g. Weighing ~2.1 kg as a fully operational system, the FIRM comes with a zippered carrying bag for easy storage. Each component is discussed in further detail.

2.1 Face Piece

The face piece is constructed of a rigid, optically clear, injection-molded polycarbonate. It provides a chemically impermeable interface to the hood and covers the entire face. The face piece serves as a visual binocular lens and a mounting point for the nosecup and exhalation valve assembly and contains pass-through ports for both the inlet air supply and drink tube. When worn properly, the face piece is in a vertical position, minimizing any glare. Both internal and external surfaces of the face piece are coated with a diamond-hard coating to prevent fogging. This wide transparent face piece provides the equivalent of an almost unhindered visual field of view, yet the wearer and his facial expressions can be easily recognized.

Figure 1. Front view of the FIRM. The blower is shown with two different canisters (Racal F45 on right; military C2 on left) to demonstrate its ability to use standard North Atlantic Treaty Organization (NATO) thread.

Figure 2. Right-side view of the FIRM.

2.2 Exhalation Valve Assembly

The exhalation valve assembly consists of a valve seat, disc, and cover. The valve seat is molded and totally recessed 8 mm into the face piece. The valve seat features a standard crisscrossed valve disc support 2 mm in width, plus another circular valve disc support 1 mm in width. The outer edge of the circular support is 1 cm from the center of the 13-mm-radius valve seat opening. This arrangement prevents any portion of the valve disc from remaining in the open position (i.e., curling or sticking together due to moisture in exhaled air, being sucked into the seat, etc.) when the wearer is breathing hard. The elastomeric exhalation valve disc is a blind pocket, snap-on, four-step ramp, multithickness design. The Nylon 66 snap-on outlet valve cover is removable for easy cleaning and maintenance. The upside-down teardrop shape of the valve cover, combined with the recessed design of the valve seat, forces exhaled air to be discharged only in the forward direction through a patterned series of 2-, 3-, 4-, and 5-mm-diameter holes. The smallest holes are located toward the periphery, beyond the outer edge of the exhalation valve seat.

2.3 Drink Tube

The drink tube is 42.5 cm long, with an internal diameter of 3.2 mm, and an external diameter of 7.9 mm. It extends from a metal nipple molded into the face piece below the air supply hose to a plastic plug cap that can connect to most commercially available soda or water bottles (e.g., Coca Cola soda, Evian Natural Spring water, etc.). The female thread of the cap will mate with the male thread of the soda/water bottle once both the drink tube plug cap and bottle cap are removed. Fluid will only flow when the in-line ball valve is folded on itself, and a reduced pressure is created by sipping on the end of the drink tube in the nosecup. The plastic drink tube mouthpiece in the nosecup does not interfere with wearing the mask. To bring the mouthpiece into position, the nosecup must be pushed against the face so the teeth can grasp the mouthpiece. The drink tube is held to the blower hose by a Velcro attachment ring mounted on the blower hose.

2.4 Nosecup

The triangular-shaped silicone nosecup is 120 mm long and 90 mm across at its widest point. It has a rolled internal peripheral seal, 25 mm wide and 0.5 mm thick, to comfortably accommodate most faces without leakage. It also has a flared chin cup extending 65 mm from the base of the nosecup. The nosecup is attached to the face piece by friction, stretched around a 55-mm-diameter molded collar. There are two plastic inhalation valve seats with valve discs located ~1 cm from the vertex on either side of the nosecup. The valve seats have a central hub with eight radial spokes. The valve discs are 23.8 mm in diameter and 0.4 mm thick, with a mushroom stem design that is pressure fit through the hub of the valve seat. The interior and exterior surfaces of the valve discs are smooth, except for the date of manufacture on the interior surface.

2.5 Neck Dam

The silicone neck dam is 0.50 mm thick with a 6-cm diameter die-cut opening for the neck seal. The neck dam is sufficiently elastic to allow the head to pass through during donning and doffing, yet maintains a comfortable and secure neck seal. The unstretched neck seal opening is sized slightly smaller than the cross-sectional area of the one percentile female soldier, but can comfortably stretch to fit the neck of the 99th percentile male (*4*). The neck seal features a small beaded edge to prevent tearing or ripping during donning and doffing. The neck dam is glue bonded directly to the inner surface of the hood. The width of the bonded surface is ~1 cm around the entire peripheral edge of the neck dam.

2.6 Hood

The hood is made of an impermeable, trilaminate, fire-resistant Nomex/Saranex/Jersey material that is functional in temperatures from –34 to +50 °C for at least 12 hr. The hood is large enough to accommodate the 99th percentile male head (*4*), and the material gathers to adapt to the 5th percentile female head using the single adjusting strap. This untethered polypropylene strap passes through two in-line cloth guide channels stitched to the external surface of the hood. These channels are located on each side of the central seam on the back of the hood, just below the ears. The strap also passes through two roller quick-release buckles attached to the face piece mounting band at the level of the middle of the nosecup. This strap arrangement permits tightening the mask to any adult-sized head by adjusting either one or both ends of the strap. By pushing both buckle tabs forward, the tight strap is immediately released for easy mask doffing.

All hood seams are tightly stitched before internally covered with tape and a luting compound. A rubber ring is lap bonded to the edge of the hood face piece opening. A 10-cm portion of this edge ring is expanded internally to provide both a reinforced forehead cushion and a sweat diverter to prevent forehead sweat from dripping into the eyes. This rubber hood ring is band clamped onto the external circumferential channel molded into the rigid face piece to provide a mechanical (i.e., nonbonded), agent-resistant seal. This Nylon 66 band has the manufacturing date located on the lower left side of the band, the name of the manufacturer and mask model number on the lower right side, and the tightening screw at the bottom of the face piece. The hood also contains three transparent flexible plastic pockets (4.5 cm wide and 5.0 cm high), externally stitched on either side of the head and on the back of the neck below the neck dam. Because of input provided by potential users during development, these pockets can be used for identification using color-coded or numbered inserts. The hood has a cowl extending beyond the circumferential edge of the neck dam. Over the back and chest, this cowl extends a distance of 15 cm. Over the shoulders, this cowl extends ~10 cm beyond the neck dam.

2.7 Pressure Relief Valve Assembly

Located at the back of the hood, the pressure relief valve vents excess air out of the hood (i.e., air that is not inhaled into the nosecup). Its valve seat and valve disc configurations are identical to

the exhalation valve seat and disc, except for the size of the recessed opening beneath the valve cover. The pressure relief valve's recessed opening is 35 mm in diameter, compared to the larger 46-mm-diameter opening on the exhalation valve. The pressure relief valve cover is domed in design with a 71-mm diameter and 21-mm crown. Its hole size pattern is the reverse of that found on the exhalation valve cover, but allows for omnidirectional flow when the valve is open.

2.8 Blower Assembly

The single-speed blower is issued with two replaceable RACAL F45 filter canisters capable of protecting against military chemical/biological warfare agents as well as hazardous commercial chemicals. Because the blower has standard NATO and European Norm (EN) filter threads (*5, 6*), it can use any filter employing that threaded configuration. Powered by a military/ commercial BA 5800/U lithium sulfur dioxide battery, the blower is reported to provide a continuous airflow of 90 L/min into the face piece/hood for 15 hr. The blower motor is contained inside a plastic housing, along with a sealed internal plenum extending from the filter canister attachment points to the hose fitting attachment point. If the outer case of the blower is damaged or breached, the filtered air path to the mask will remain uncontaminated. The outlet of the blower plenum also contains the same male NATO or EN thread that connects with the female thread in the hose connecting the blower to the face piece. The agent-resistant, elastomeric hose is 62-cm long with an internal diameter of 22 mm. Kink-resistant and corrugated, the hose is connected with a clamp to the rigid face piece just below the nosecup. If necessary, the wearer could disconnect the hose from the blower and substitute one of the filter canisters to reconfigure it as a negative pressure mask system. The total weight of the blower assembly is ~1.35 kg. The weights of each component are 600 g for the blower, 325 g for each RACAL F45 filter canister, and 75 g for the BA 5800/U battery.

The blower can be attached to the user's body in several ways. A 152-cm adjustable belt with movable snap-on buckles is provided, which connects to loops on the blower housing. It can be worn either around the waist (Figure 1) or over the shoulder and under the opposite arm to keep the blower out of the way while performing specific tasks. If the blower is worn around the waist, a second short Velcro strap is available, which passes through other loops on the bottom of the blower and wraps around either leg to anchor it and minimize interference. If the wearer has donned a vest, snap rings can be used to attach the blower to the front or back of the vest to keep it out of the way. An optional cloth back frame is available to mount the blower on the back (Figure 3).

2.9 Carrier Bag

The zippered carrier bag is fabricated from a durable, water-resistant fabric. Amply sized in a roughly cubic shape (28 × 28 × 30 cm), the carrier bag unzips in either direction around the top, providing easy access to the mask and its ancillary items. The carrier bag also features a single 4-cm-wide × 60-cm-long polypropylene strap, extending over the top of the bag for hand

Figure 3. FIRM blower mounted in optional cloth backpack.

carrying and stitched to the lateral sides of the bag. Fully loaded with the mask, blower, filters, battery, and operator's manual, the carrier bag takes up a volume of ~23.5 L.

2.10 Principle of Operation

When the blower air enters the mask at 90 L/min, it deflects off of the nosecup and floods over the interior surface of the face piece, which prevents fogging. A portion of that airflow is inhaled into the nosecup through the nosecup inhalation valves and is exhaled through the exhalation valve assembly. Whatever airflow is not used for respiration (i.e., air that does not enter the inhalation valves of the nosecup) exits the hood through the pressure relief valve at the back of the hood, as illustrated in Figure 4. A more detailed description of the FIRM, including level 1 drawings, can be found in the DEA Research and Development report (*7*).

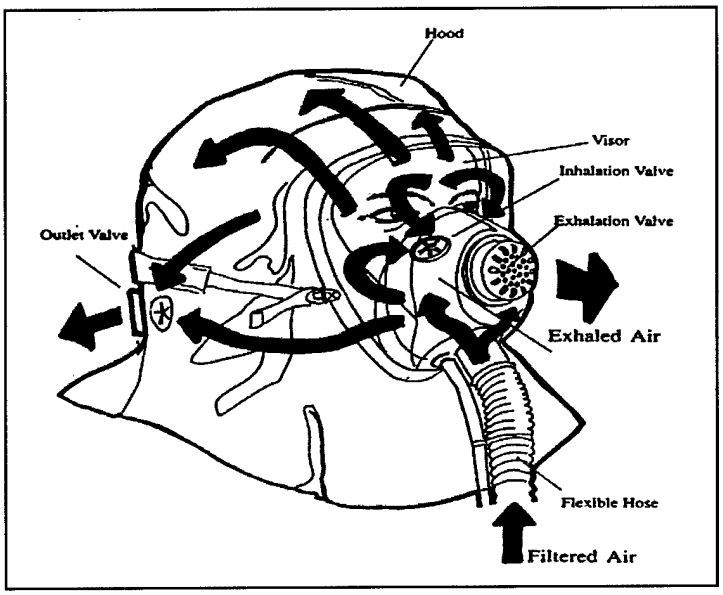

Figure 4. Illustration of airflow pattern in the FIRM.

3. Methods

In this study, the FIRM was physiologically evaluated in three basic areas: respiratory/exercise function, vision, and acoustics. Each area was investigated extensively in compliance with a previously approved human use protocol to determine the FIRM's performance characteristics. Five masks were randomly chosen from a group of 25. Fifteen trials were conducted on these five masks to determine any variation between masks. Two of those masks were tested with six and four human subjects, respectively, to determine if there was any variation between subjects using the same mask. Three subjects wore the same mask twice, while two subjects wore two different masks in the test group to determine within subject and within mask variation. Each subject was tested both with and without a mask to serve as his own physiological baseline control. Subjects were selected at random with the following constraint: two different subjects participated each day, completing both a baseline control and FIRM evaluation in random order.

Twelve adult male volunteers served as test subjects. Six were professional firefighters/ emergency medical technicians, and six were engineers/scientists. This subject mix was chosen to represent the type of population expected to use this respirator. Each subject had at least 5 years of experience wearing a respirator, many on a daily basis. Their average age was 38 years old. Full anthropometric data are presented in Table 1. The subjects had at least 6 hr of sleep within the previous 12 hr before reporting for the test. Three subjects had mustaches. All were currently nonsmokers. The two who had previously smoked had not done so within the last 3 years. All testing was conducted at an ambient room temperature of 23 ± 1 °C. During testing, the subjects wore breathable athletic sweat pants and shirts to minimize any heat stress due

Table 1. Subject anthropometric and assigned FIRM data.

Subject	Age (yr)	Height (cm)	Weight (kg)	Neck Size (cm)	Glasses	Mask No.	Blower No.
A	48	171.5	86.0	42.0	Yes	25, 18	12, 20
B	22	177.8	91.8	43.0	No	17, 18	20
C	44	170.2	91.8	42.0	No	25, 25	12
D	45	186.1	136.0	45.5	Yes	25, 25	12
E	29	192.4	83.4	39.5	No	25	12
F	48	174.0	90.0	45.5	Yes	17	20
G	47	179.7	108.0	44.0	Yes	17	20
H	51	168.3	73.0	39.0	No	35	24
I	20	186.1	78.8	38.0	No	35	24
J	40	189.9	114.2	44.5	No	35	12
K	42	168.0	90.0	34.5	No	30	17
L	20	182.9	83.2	40.0	No	35, 30	24, 17

to the clothing; this gave them the feel of body movement resistance produced by their regular work ensembles.

3.1 Respiratory/Exercise Tests

Ten volunteer adult males served as test subjects (F and K did not participate). Pedaling a Monark 818E ergometer at 60 rpm, in conjunction with a Qwick Time electronic metronome, created the energy expenditure.

To evaluate FIRM's capability regarding respiration and exercise, the subjects participated in the following 90-min protocol (Table 2):

Table 2. Test activity protocol.

Activity	Time (min)
Seated rest (baseline)	10
Working at 50 W	30
Seated rest	10
Working at 100 W	30
Seated rest	10

Each subject randomly went through the test once as a baseline control, and once while wearing the FIRM with the blower on. Five of the subjects repeated this same protocol a second time, with and without the FIRM, to determine whether within subject and between subjects variation was equal to or greater than the responses seen when the FIRM was used. Thus, a total of 15 trials were conducted with the FIRM worn.

A preliminary NIOSH test of the FIRM prototype on their breathing simulator showed that CO_2 could build up to 7% in the hood over a 20-min period if either the blower was off or nonfunctioning, or the nosecup was loose. Because this 20-min period would give the wearer

adequate time to exit to a safe environment if the blower failed, NIOSH did not consider this a serious hazard (*3*).

To address this potential problem, the protocol was extended an additional 60 min to assess the level of CO_2 buildup with the blower off, both at rest and at exercise, as shown in the following results in Table 3.

Table 3. Extended protocol to evaluate CO_2 build-up.

Activity	Time (min)
Blower off, at rest	20
Blower on, at rest	15
Blower off, working at 50 W	20
Blower on, at rest	10

All 15 trials continued the test with the blower off for 20 min, while only seven trials were run with the blower off while exercising. The blowers were turned on for 10 min after each of the two 20-min periods, with the blowers off, to verify that the CO_2 concentration within the hood would return to the zero baseline level if it had risen while the blower was turned off.

During this portion of the study, both oxygen and CO_2 concentrations were continually measured inside the FIRM in the region between the nosecup inlet valve and the right eye. An Ametek S-3A/II oxygen analyzer and a CD3A CO_2 analyzer were used, and their output recorded on a SOLTEC two-channel recorder. The 1.6-mm-diameter sample collection tube was taped to the inside of the FIRM lens, but bent 1 cm away from the lens surface. The air sample collection flow rate was 100 mL/min, creating a detection response time of 3 s. Both instruments were calibrated with 99.995% nitrogen to establish a zero baseline, and then calibrated with a 5% CO_2 and 12% oxygen mixture, as well as with air.

A 4.75-mm-diameter, flat-bead, Yellow Springs Instrument Company no. 427 thermistor probe was also attached at the same point to measure the internal hood air temperature. The bead was turned toward the face to eliminate thermal reflection from the face piece surface. The air temperature parameter was continuously measured with a Cole-Parmer portable thermistor thermometer, model no. 8502, connected to a Linear recorder. The FIRM air sampling tube and thermistor exited the hood between the neck dam and skin at the anatomical groove between the right carotid artery and jugular vein to maintain the neck seal.

Heart rate was also continuously monitored using a Gould Instrument Biotach, no. 136615-65. The electrocardiogram signal, from which the heart rate was derived, was monitored using a three-lead arrangement with one electrode on each clavicle approximately halfway between the sternum and acromioclavicular joint, and the third lead on the left external oblique muscle immediately above the iliac crest. The heart rate was measured as a rolling 5-s average, triggered by R-R intervals.

Room temperature was recorded every 15 min, employing a Yellow Springs Instrument Company no. 405 thermistor probe connected to another channel of the Cole-Parmer portable thermistor thermometer used to measure the hood's internal temperature. All test instruments were calibrated before and after every test.

3.2 Vision Tests

The same 10 test subjects participating in the respiratory/exercise portion of the test also participated in the vision evaluations. They were joined by two additional subjects in their forties, one female (K) and one male (F). Four subjects wore glasses and continued to wear them under the FIRM during the vision tests. All subjects repeated each vision test three times while wearing the FIRM and three times without wearing a mask.

Static visual acuity (*8, 9*) was measured by projecting Landolt "C" and "E" letters, as well as letters and numbers of the Snellen chart, using a Reichert projector. Color acuity (*10–12*) was measured with both the standard Ishihara "Test for Color Blindness" (1993 edition of 38 charts) and the Farnsworth-Munsell "Dichotomous Test for Color Blindness" (Panel 15). The Howard-Dolman method (*13–15*) was used to measure depth perception at infinite focal length. Both the Frisby Stereo test (*16*) and the Lang Stereo test (*17*) were used to measure this same parameter at close range (0.5 m). The ability to employ the entire visual field through the FIRM lens was measured using the Esterman field test (*18, 19*). The lateral and inferior fields of view were measured with a Marko Instrument, Inc., Goldman projection perimeter (*20*) using a white light target stimulus of size 1-3b. The ability to see through glare with the FIRM was measured with the Pelli-Robson Contrast Sensitivity chart (*21*) produced by Clement Clark, Inc., Columbus, OH.

3.3 Light Transmission/Haze Measurement Tests

Light transmission through the mask, as well as haze in the lens, was measured with a BYK Gardner Model XL211 HazeGard Meter (*22*) in conjunction with American National Standards Institute (ANSI)/American Society for Testing and Materials test method D1003-61 (*23*). The lens areas in the face pieces used for testing are identified in Figure 5.

3.4 Acoustic Tests

Six subjects were given the Modified Rhyme Test (*24, 25*). The test was conducted while the subject was wearing a FIRM with the blower on, and the unmasked speaker spoke the monosyllabic test words. The test was then conducted with the speaker wearing a FIRM with the blower on and the subject wearing no mask. The test was repeated a third time with both the subject and speaker masked and their blowers on. The same tests were repeated with the blowers off. The tests were conducted in a large open field with ambient noise at 40 dB.

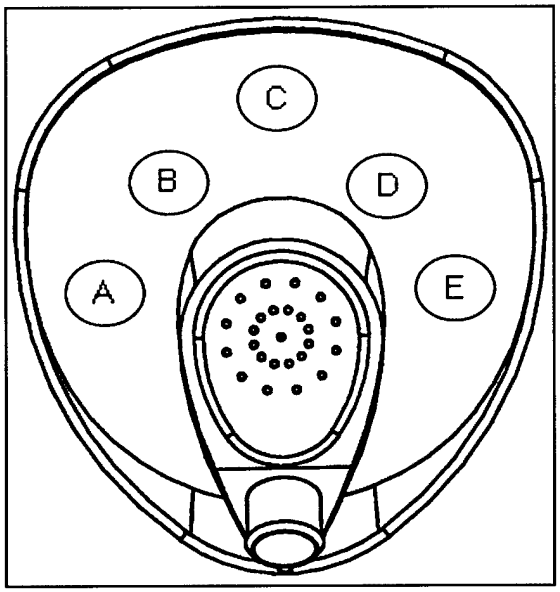

Figure 5. Light transmission/haze measurement locations on the FIRM face piece.

3.5 Drinking Tests

At the end of the test, all subjects had to consume 330 mL of bottled water through the drink tube/bottle cap mechanism. To do this, they opened the bottle cap, disconnected the drink tube connection cover, attached the bottle to the drink tube, took the mouthpiece between their teeth, opened the check valve, and drank the water.

3.6 Battery Life Tests

Three new batteries were removed from the manufacturer's packaging and each was installed in a blower assembly. The blower switch was activated in conjunction with a stopwatch, and the blower operated for 10 hr each day until the blower stopped.

4. Results

4.1 Respiratory/Exercise Tests

The oxygen and CO_2 concentrations in the hood did not essentially change from normal external ambient conditions (20.9% oxygen and 0.0% CO_2) while the blower was on during both the rest periods and the 50- and 100-W work periods (Figures 6 and 7). There was no physiologically significant difference in internal oxygen and CO_2 concentrations between the FIRMs, or within FIRMs when worn by the same or different subjects.

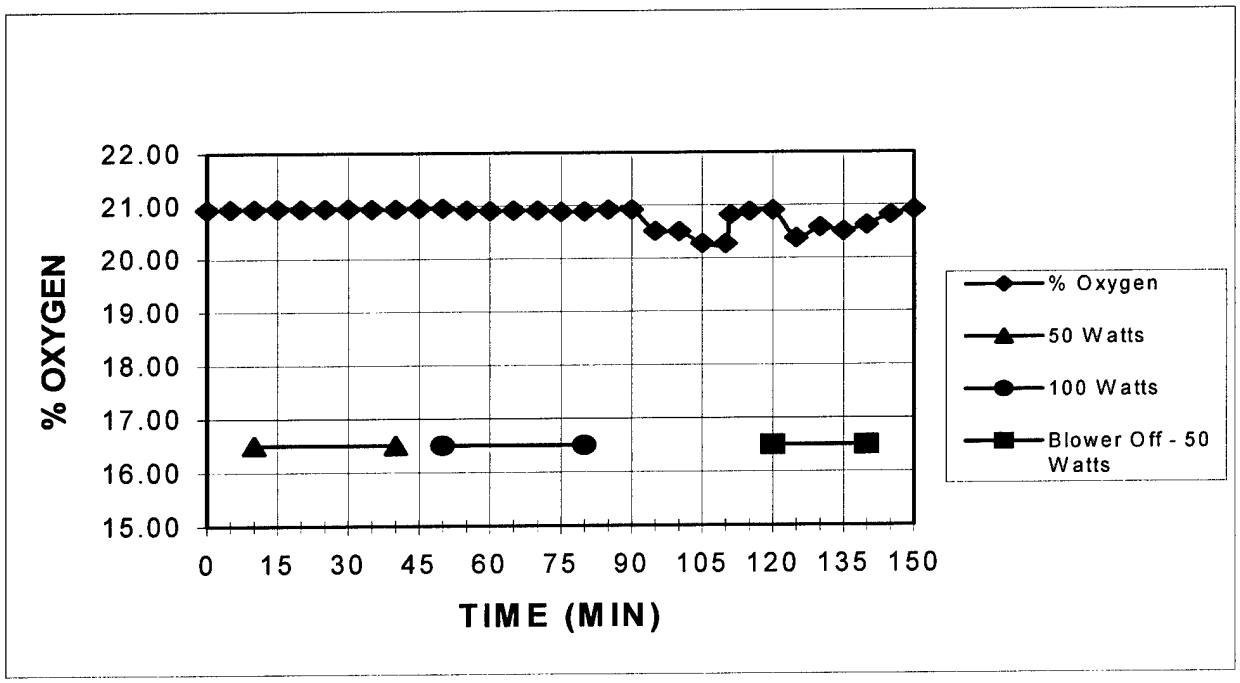

Figure 6. Oxygen concentration within the FIRM face piece at different exercise and blower conditions.

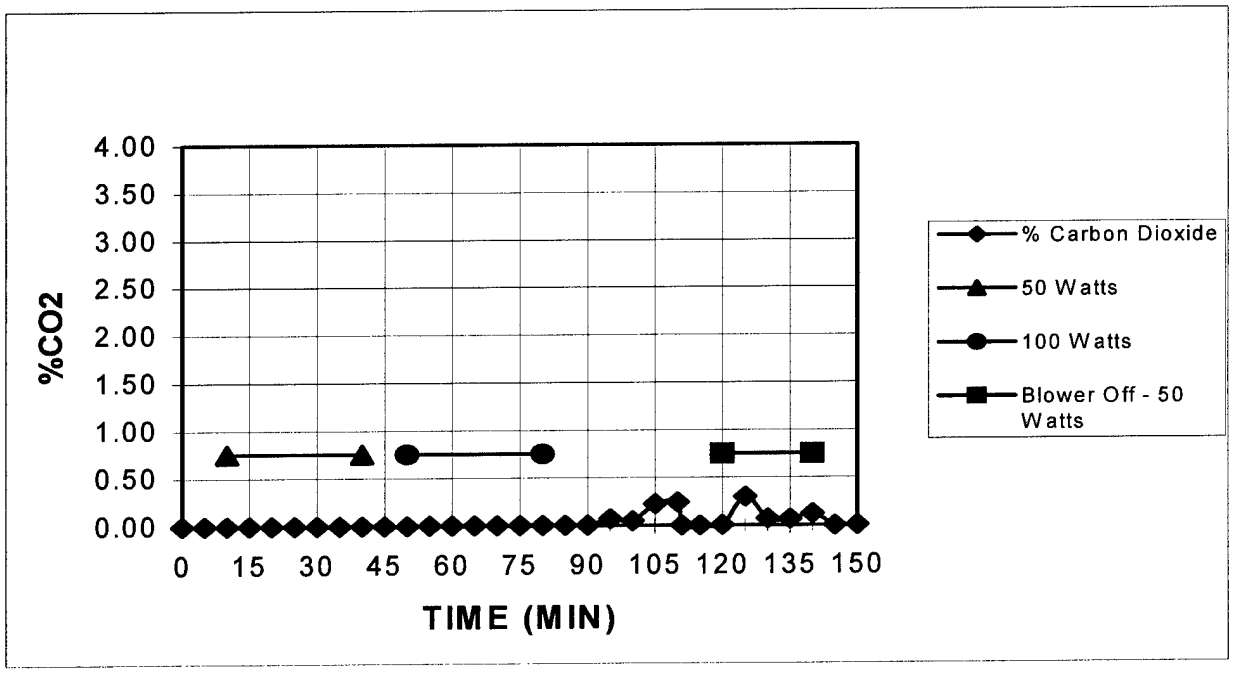

Figure 7. CO_2 concentration within the FIRM face piece at different exercise and blower conditions.

The average oxygen concentration within a FIRM fluctuated between 20.93% and 20.94%, while the blower was on, at rest, and during the lower level of exercise. When performing the 100-W workload, the oxygen concentration averaged 20.83% over the 30-min period. This slight oxygen concentration decrease started within the first 10 min of the heavier workload and fluctuated about that value for the remainder of the exercise period. Two subjects, C and E, each presented the lowest oxygen concentrations of 20.73% and 20.76%, respectively, for one 5-min recording period, but recovered to higher values during the next time period. All oxygen concentrations within the FIRM returned to the ambient 20.94% values within the first 5 min after the exercise stopped.

The oxygen concentration in the FIRM only diminished when the blower was off. When the FIRM was worn at rest with the blower off, the oxygen concentration declined to an average of 20.2%, then stabilized for that 20-min period. The oxygen concentration within the FIRMs of four of the subjects declined to between 19.00% and 19.67% during one 5-min period of the resting blower-off condition from a previously stable higher than 20.4% concentration. When these four subjects tightened the straps on their FIRMs, the oxygen concentration immediately rose back to the 20.5% concentration. During exercise with the blower off, the average oxygen concentration initially declined to 20.4% during the first 5-min, but then stabilized to 20.5% for the remainder of the 20-min period.

As seen in Figure 7, the average CO_2 concentration within the FIRM face piece, while the blower was on, remained at ambient environmental levels during both the resting and the two exercise periods. Again, there was no significant physiological difference in internal CO_2 concentrations between FIRMs or within FIRMs when it was worn by the same or different subjects. In one subject, however, talking caused a pulsating trace of CO_2 within the FIRM face piece to an average episodic level of 0.03%. When the subject stopped talking, the CO_2 level returned to external ambient levels. This phenomenon was observed a second time in the same subject wearing the same FIRM. This phenomenon was not observed in any of the other subjects when they were talking with the investigator or trying to convert scrambled letters into words. The CO_2 levels did not rise in the face pieces of the four subjects who had tightened their hood straps during the test, except for the subject who talked.

During the 20-min period when the blower was turned off and the subjects were sitting quietly (i.e., resting), CO_2 rose to an average level of 0.29% within the FIRM face piece. While the blower was turned off during the 20-min period when the subjects were exercising at 50 W, CO_2 never exceeded an average level of 0.16% for all 10 subjects.

When the subjects were shallowly breathing (primarily while sitting quietly with eyes closed), the nosecup inhalation valves "cracked" slightly, allowing some of the nosecup air to flow backward into the face piece area. Five of the subjects exhibited a regular breathing pattern within this face piece (i.e., CO_2 concentration pulsations averaging 11 breaths/min) when the blower was off during rest, but not during exercise.

One subject had an average level of 0.05% CO_2 in the hood for 5 min, midway through the 30-min exercise at 100 W, but this was not seen when the test was replicated by the same subject wearing another FIRM. The subject did not adjust the hood strap after detecting CO_2 in the FIRM. Several other subjects wore the previous FIRM without exhibiting the presence of CO_2 in the face piece area.

The average internal temperature within the face piece rose slightly (0.7 °C) from 24.6 to 25.3 °C during the two 30-min periods of exercise with the blower on, as seen in Figure 8. The standard deviations during this portion of the testing ranged from 1.17 to 1.66 °C. The temperature within the FIRM always returned to the baseline 24.6 °C during the intermittent rest periods. At rest, with blower off, temperature again rose (2.8 °C) from 24.5 to 27.3 °C, then stabilized at that level for the last 5 min of that 20-min period. In the 15 trials with the blower off at rest, the standard deviation ranged from 1.05 to 1.47 °C over the course of the 20-min period. With the blower off during exercise and only seven subjects participating, temperature within the face piece rose 3.1 °C to an average 27.9 °C when starting from a baseline 24.85 °C. The ambient room temperature remained at 23 ± 1 °C during the test sessions.

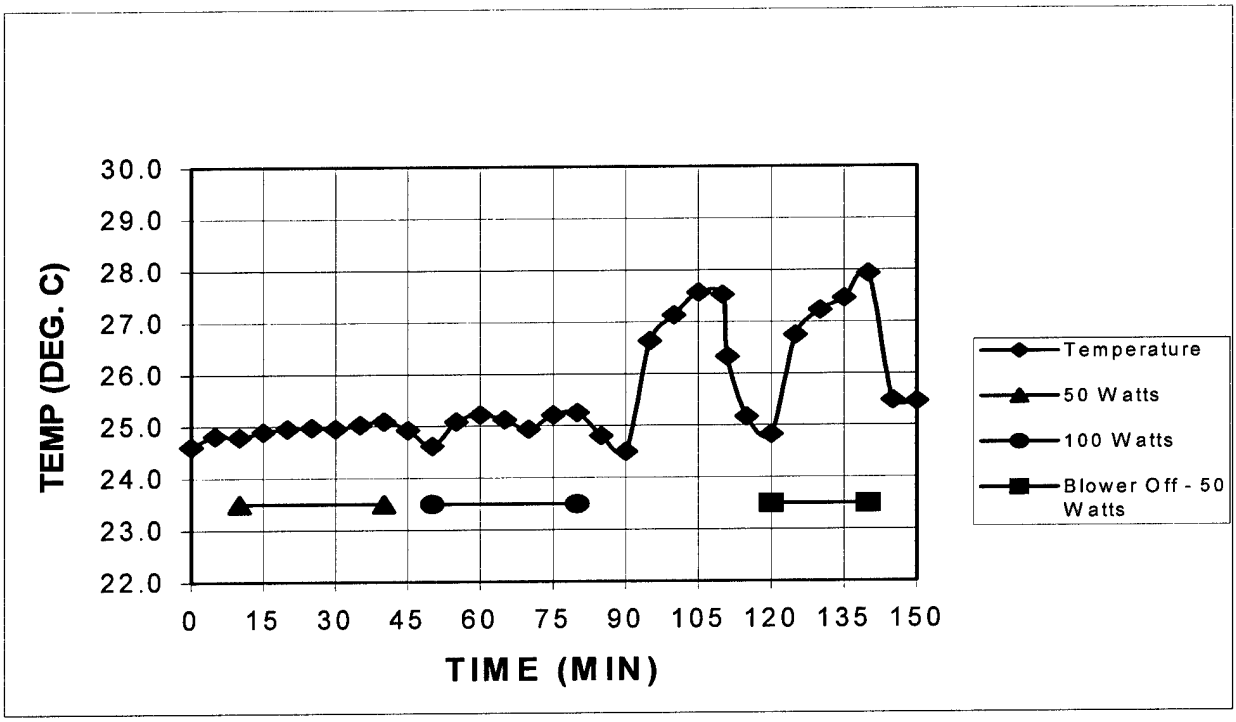

Figure 8. Internal temperature within the FIRM face piece at different exercise workloads and blower conditions.

Figure 9 and Tables 4 and 5 present the average heart rate of the test participants while wearing the FIRM over the duration of each test. As expected, the heart rate was elevated ~30 beats/min over the baseline resting condition with the blower on during the 50-W workload and was elevated ~60 beats/min during the 100-W workload.

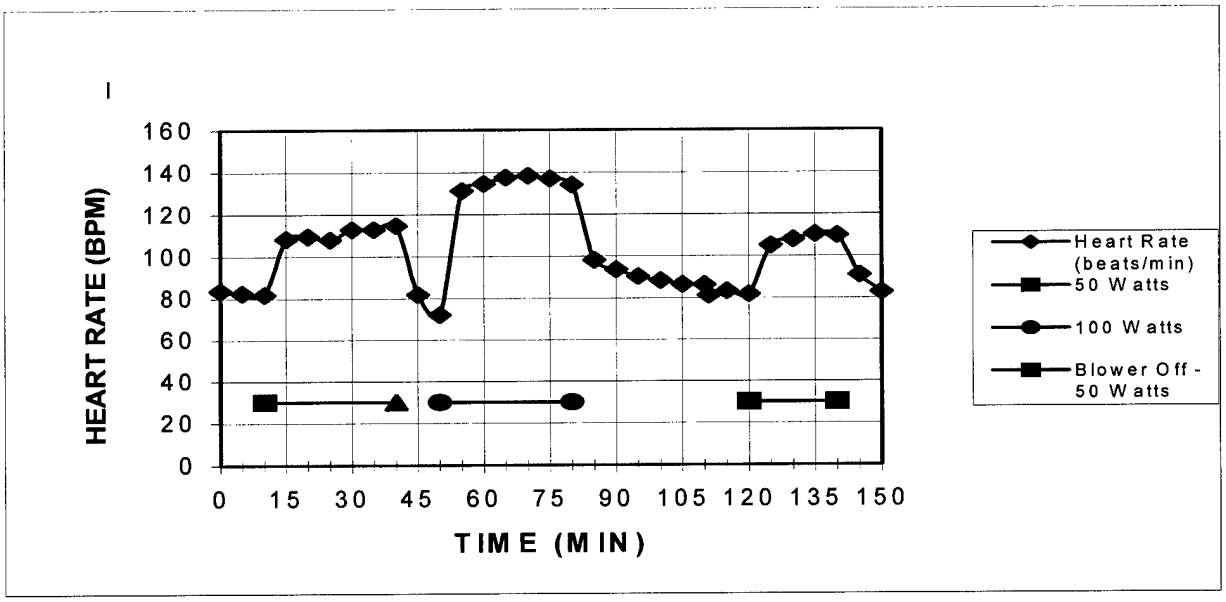

Figure 9. Subject heart rate wearing the FIRM at different exercise workloads and blower conditions.

Table 4. Average heart rate and control differential at 5-min intervals.

	Rest			50-W Workload						Rest		100-W Workload						Rest	
Time (min)	0	5	10	15	20	25	30	35	40	45	50	55	60	65	70	75	80	85	90
Wearing FIRM	83	82	82	108	109	108	113	113	115	82	72	131	135	138	138	137	134	98	94
Diff. from control	5	3	1	4	4	1	5	4	5	2	0	6	4	4	2	3	1	4	2

Table 5. Average heart rate with the blower off at 5-min intervals.

	Rest		Rest Blower Off				Rest			50-W Blower Off					Rest
Time (min)	85	90	95	100	105	110	115	120	125	130	135	140	145	150	155
Wearing FIRM	98	94	90	88	86	86	81	83	82	105	108	110	110	91	83

When heart rate values wearing the FIRM were compared to unmasked control values of the same subject over the exercise portion of the study, it was observed that the average differential heart rate was 0.9–6.0 beats/min higher when wearing the mask.

4.2 Vision Tests

When the FIRM vision capabilities were evaluated on 12 subjects, there was no observed degradation of visual capabilities from their control values measured without a mask.

Using the Ishihara test (*10*) and the Farnsworth-Munsell test (*12*), subject B was identified as color blind; therefore, subject B's responses were not included in the FIRM color vision analysis. Using the Farnsworth-Munsell color test, 10 of the 11 subjects showed no change in their ability to detect subtle color differences when wearing the FIRM (Table 6). Subject E passed this subtle color test without the mask, but showed a potential problem with the color blue when the mask was worn.

Table 6. Vision capabilities of the FIRM.

Parameter	Test Used	Status	
		Average Test Result	Unmasked Control
Visual acuity	Snellen letters	20/18.9	20/20.6
—	Snellen numbers	20/19.7	20/20.6
—	Landolt C's and E's	20/17.5	20/18.8
Color acuity	Ishihara charts	Passed	Passed
—	Farnsworth-Munsell	Passed	Passed
Depth perception	Howard-Dolman	1.37 mm	0.9 mm
—	Lang stereotest	Passed	Passed
—	Frisby stereotest	Passed	Passed
Contrast sensitivity	Pelli-Robson	1.82	1.88
Visual efficiency index	Lateral	87%	100%
—	Inferior	96%	100%
Full lens utilization	Esterman field	943%	100%

Analyzing the color vision data from the Ishihara 38 plate color test, 10 of the 11 subjects showed no difference in their color acuity while wearing the FIRM compared to their control tests (Table 6). Subject A was unable to identify two Ishihara color plates in the control test and one plate while wearing one FIRM. On another day, when the tests were repeated in both the morning and afternoon, subject A was able to pass the Ishihara test both as a control and while wearing a second FIRM. Subject A also passed the Farnsworth-Munsell test both as a control and while wearing two different FIRM masks. Subject E, who had shown a Farnsworth-Munsell test deficiency for detecting blue while wearing the FIRM, easily passed the Ishihara bright color charts wearing the same FIRM. The test data indicate that the polycarbonate lens of the FIRM does not interfere with color vision.

Static acuity was tested with three different types of symbol groups: alphabet, numbers, and directional "E." These tests were conducted with the subject wearing corrective lenses (glasses only) under the FIRM, if the subject normally wore them. There was essentially no difference in the ability to read numbers, letters, or directional "E." The average unmasked control visual acuity was 20/20.6 in 48 tests. Wearing the FIRM slightly increased average visual acuity to a 20/18.9 Snellen score over the same number of trials. This one-line difference is not significant when considering that it is within same subject variability during repeated tests. Four of the 12 subjects (B, C, E, and H) showed a consistent one-line decrement in visual acuity for all three symbol groups while wearing the FIRM in one or two separate trials when compared to controls.

This was balanced, however, with one subject consistently showing a one-line acuity improvement and three others showing a partial improvement (two out of three symbol group tests) when wearing the FIRM, compared to control acuity data values. This difference in masked visual acuity could not be attributed to the one-size-fits-all neck dam gently constricting the major cervical circulatory vessels (*26*). Those subjects showing an acuity loss essentially had the same overlapping range of neck circumferences (39–43 cm) as those who showed improved visual acuity (38–44 cm) while wearing the FIRM. Those subjects who wore glasses exhibited neither a decrement nor increment in visual acuity with the mask. Any minor inconsistency could not be attributed to the mask; any deviations from unity were balanced out by some subjects showing a one-line increase in visual acuity and others a one-line decrease.

Depth perception measures a subject's ability to distinguish objects being in the same focal plane when presented at a distance of infinite focal length (in this study, 6 m). All 12 subjects were able to line up the two arrows within the 3-cm distance required to pass the U.S. Air Force (USAF) pilot depth perception regulations (*15*) when manipulating the arrows from a distance of 6 m. On average, the subjects were able to get the two arrows within 1.37 mm of each other with wearing the mask, compared to 0.9 mm without it.

Both the Frisby Stereo test (*16*) and the Lang Stereo test (*17*) were used to identify problems with close range (0.5 m) depth perception. The Lang Stereo test requires the binocular identification of three objects (cat, star, and car) within a framework of alternating white and black bars. The Frisby Stereo test uses a series of three transparent plastic cards of different thickness (2, 4, and 8 mm), each containing four square random spot patterns printed on one side and only one of those squares with the same pattern on the opposite side of the card to give it depth. All 12 subjects passed these tests when subjects wore the FIRM. Subject C failed the Lang Stereo test with one mask and passed it the second time wearing the same mask. Subject C passed the Frisby Stereo test both times.

Contrast sensitivity is the ability to distinguish letters or objects when there is the equivalent of various intensities of bright light shining in the eye. The Pelli-Robson test (*21*) simulates this by displaying groups of letters in different gray-scale intensities. Wearing the FIRM did not change the contrast sensitivity scores observed in each subject when conducting the same test series without a mask (Table 6).

The Esterman binocular field test (*19*) was used to determine if the full lens was usable without distortion. The only areas of any distortion noted were in the regions of both the right and left lower lateral quadrants. Observed in 14 of the 16 FIRM tests, this distortion amounted to an average 5.7% loss of the visual field with a range of 0–18 designated Esterman areas being affected. Only seven of the subjects experienced distortion of >5%, primarily because those affected had a narrow face. This distortion was due to the sharp corner molded into the face piece at these locations. This distortion only became a problem when the subject was looking

downward as far as possible without moving the face in that direction. None of the subjects complained that this distortion was annoying, or that it interfered with their work.

Peripheral field of vision data, with and without wearing the FIRM, were collected on 12 subjects for both the right and left eye separately, and then they were combined using the common focal point for data overlap. Because the FIRM incorporates a single lens construction, only the binocular visual peripheral field was reported. For easier data presentation, the peripheral field of only one subject was presented as Figure 10. These data, however, are consistent with the findings on the other 11 subjects. When the FIRM was worn, the peripheral visual fields were almost identical to the unmasked control visual fields in the same subject, averaging 97% of the unmasked controls on the same subject. The subjects were able to obtain a full 90° lateral field as well as a 55° superior field and 60° inferior field when focusing directly ahead. There was a slight loss (~15°) of peripheral visual field in the lower lateral quadrant on each side of the face. This was because the face piece narrowed in this region and the folded corner molded into the face piece at these locations. When the mask was tested to determine if it permitted an extended field of gaze (*27*), it was found that 90° was the lateral limiting angle of the normal field of view as well as an extended field with eye rotation.

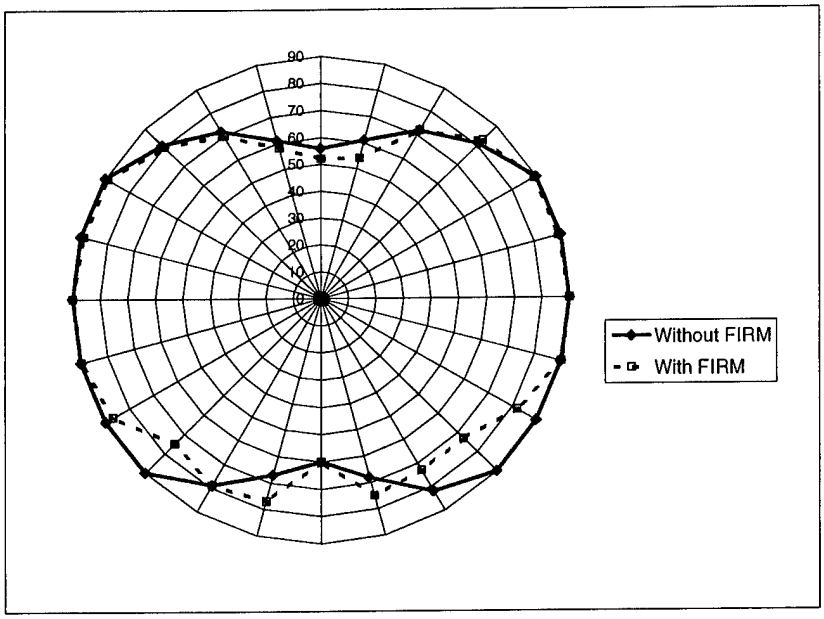

Figure 10. Visual peripheral fields with and without the FIRM.

The FIRM's average lateral visual efficiency index (*27*) was 87% of the same subject's unmasked control value. This decrease was due to the loss of a small lower portion of the lateral field of view described previously. The FIRM average downward visual efficiency index was 96% of the unmasked control in the same subject. The downward visual field was slightly larger than normal control vision over a 60° arc.

4.3 Light Transmission/Haze Measurement Tests

Light transmission through the face piece averaged 92.9% for five masks; each was tested five times. The range was 92.0%–93.1%, and the standard deviation was ±0.14%. The between mask variation was ±0.09%, and the within mask variation was ±0.37%. The FIRM meets the 87% minimum light transmittance requirements from ANSI test method no. Z87.1 (*28*) through the face piece.

Light scattering (haze) averaged 0.43% for the same five masks; each mask was tested five times by the ANSI test method (*28*). This level of haze was well within the maximum 3.0% permissible levels to meet this ANSI Standard (*28*). This value was due to a high reading for three of the masks in the face piece area immediately above the nosecup (location C of Figure 5). If these three elevated data readings (1.2%, 2.8%, and 1.4%) were removed from the computation, the haze readings would average 0.24%.

4.4 Acoustic Tests

The ability to communicate through the FIRM is presented in Table 7. While wearing a mask with the blower off, the ability to speak intelligibly to someone not wearing a mask was not statistically significant from a conversation between unmasked people. More than 90% of the monosyllabic words were communicated correctly through the FIRM. When both the speaker and the listener communicate through the FIRM without either blower activated, intelligibility decreased slightly, but was still in the "good" range. If both persons communicate while wearing the FIRM with the blowers on, intelligibility sharply decreased to the 40% level for both the speaker and the listener. An unusual communication problem was observed when a person wore the FIRM with the blower on while another person was unmasked. If the masked person was the talker, communication was almost normal (89%); if he was the listener, communication was poor at the 40% level.

Table 7. Communications intelligibility of the FIRM.

	Listen		
Talk	**Unmasked Control**	**Mask + Blower Off**	**Mask + Blower On**
Unmasked control	95.2	94.6	35.2
Mask + blower off	91.6	85.6	—
Mask + blower on	89.2	—	40.6

4.5 Drinking Tests

During the last rest period of the 2.5-hr test protocol, each subject drank 330 mL of water from an Evian Natural Spring Water plastic water bottle. No one had difficulty separating the bottle cap, opening the protective cap at the end of the drink tube, and attaching the bottle to the drink tube. Two of the subjects, because of their relatively flat faces, had difficulty reaching the tube mouthpiece within the nosecup. By externally pushing the face piece tightly against their faces, they were able to grasp the drink tube mouthpiece with their teeth and start to drink.

The large bore (3.2 mm) of the drink tube permitted very rapid water consumption, with everyone finishing the 330 mL in <3 min. The subjects commented favorably that it was not necessary to elevate the bottle above the mouth level to initiate drinking by gravitational flow. Water was ingested by normal mouth suction in the same way that one would drink through a soda straw. When the flexible water bottle started to collapse as water was removed, the subjects stopped mouth suction, causing the bottle to expand naturally with the return flow of air down its pressure gradient. This is in contrast to drinking through a mask from a regular military-style canteen where the subject has to crack the seal of the canteen to release the vacuum and restart gravitational flow.

None of the subjects commented that the drinking tube mouthpiece was an annoyance. During previous field trials with the prototype FIRM, a number of participants commented that the mouthpiece brushed against their face during various body movements.

4.6 Battery Life Tests

The three batteries, tested in 10-hr blocks, powered the blower continuously for an average of 23.25 hr, with a range of 22.5–23.5 hr. The power output of these batteries exceeded the 15-hr life expectancy reported by DEA Research and Development, Inc., which provides a substantial safety factor.

5. Discussion

The purpose for developing this FIRM was the necessity to equip civilian emergency response personnel with a mask that could easily meet the requirements of all its intended wearers, without restricting their off-duty, personal lifestyle (i.e., long hair, beards, mustaches, etc.) or interfering with their occupational activities (i.e., operating communication equipment, emergency first aid, etc.). The need for such a mask did not invoke much importance until chemical weapons of mass destruction were first used in a noncombat situation (*29, 30*) in Matsumoto and Tokyo in 1994–1995.

5.1 Mask Design

The concept of employing a stretchable neck dam in the FIRM to provide the protective seal, rather than relying on the current military mask in-turned peripheral seal to provide a tight facial seal, offers many advantages. Personnel who normally wore beards and mustaches, long hair, cosmetics, and prescription eyewear, as well as those who had irregular facial features (e.g., scars and surface changes due to injuries or birth defects, extremely large or small shaped noses, sharp jaw lines, high cheek bones, etc.), could now have a mask that would accommodate both their anatomical configuration and lifestyle.

The one-size-fits-all design of the FIRM eliminates the need to stock and quantitatively fit different size masks to a constantly changing workforce. Anyone can be issued one of these masks immediately, without having to be prefitted for a specific size. When personnel are issued a FIRM, they can wear their regular prescription corrective glasses underneath the mask without having to get a special pair that could only be worn with this mask.

The long operational duration filter canister blower, the transparent face piece, and the flexible neck dam instills self-confidence in the wearer, potentially eliminating a claustrophobic feeling under stress that some experience while wearing a mask. The blower provides a steady supply of fresh filtered air that is difficult to overbreathe, even at heavy workloads. The optically transparent, full face piece visor does not induce the trapped feeling that some wearers felt using the smaller paired lenses of military masks. The FIRM visor allows them to recognize, and be recognized by, one another as well as the people they are serving. The smooth hood eliminates the head strap buckle "hotspot" discomfort typically found in military-type mask suspension systems. Such "hotspots" can be distracting to the point of intolerance, resulting in the wearer removing the mask.

Current civilian work masks approved by NIOSH do not have the means for consuming fluids. Many times, the first responders will be working for long periods (up to 12 hr a day) in hot environments. The ability to replace body fluids is essential to their physiological and psychological well being. During these crises, the emergency organizations must provide their own water, rather than rely on possibly contaminated local supplies. The emergency response teams have a tendency to rely on commercially available bottled water and sodas rather than on the large water tank trucks that fill military canteens. The drink tube cap is another unique feature with the FIRM. It fits different-sized bottles from >30 manufacturers. When the FIRM is attached to commercially bottled water, drinking is easier than using the U.S. Army's military canteen nuclear, biological, and chemical (NBC) connecting cap.

A second objective for developing this mask was the need for a NIOSH-approved respirator to meet the emergency needs of the civilian community. The Occupational Safety and Health Administration (OSHA) requires that all respirators worn in the workplace meet specific requirements (*31–33*). While military masks will protect against military chemical agents, they are not NIOSH certified and do not offer some of the user requirements mentioned previously. The currently available NIOSH-approved civilian masks do not protect against military agents expected in an emergency domestic or terrorist situation. The FIRM meets both the NIOSH and the military chemical agent threat requirements.

The only metallic materials on the FIRM are the binding clamps around each end of the blower hose, the nut and bolt binding the face piece band behind the blower hose inlet, and the counter-sunk screw heads on the posterior surface of the blower housing. This satisfies the EN 136 requirement, which specifies that full face masks should not contain exposed parts made of

aluminum, magnesium, titanium, or alloys that will cause sparking and flames on frictional impact (*34*).

5.2 Test Subjects and Test Methodology

The personnel anticipated to wear this mask are civilians working in an official or volunteer capacity responding to the first several hours or days of a chemically/biologically related emergency. They include firefighters, police, hazardous materials crews, emergency response teams, rescue workers, medical staff, investigators, engineering inspectors, etc. Their work is characterized by both short and extended periods of physical exertion, operation in unfamiliar/cramped/dangerous surroundings, stress, apprehension, confusion, and possibly seeing colleagues succumbing to the unknown hazardous environment. The responders would be a heterogeneous group consisting of members of different ages, sexes, and levels of experience and training, as well as nonfamiliarity with protective equipment.

The 12 volunteers participating in this evaluation were selected based on potential occupational diversity of first responders. Six of the subjects were professional firefighters and emergency medical technicians. Three subjects were engineers/scientists who would be expected to investigate or direct responses at chemical/biological emergency situations. The other three subjects were engineers with no specific counterterrorism response training, but they had used chemical protective equipment for at least 5 years in other capacities. An attempt was made to use test subjects with a cross section of ages and anthropometric sizes; however, they had a tendency to bunch in the 20- and 40-year age groups. One subject was a female scientist with many years of experience in supervising emergency response situations and investigations. All of the subjects wore many different types of respirators during the course of their work, including negative pressure masks and self-contained breathing apparatus. The firefighters/ emergency medical technicians maintained their physical strength by exercising daily at their work stations on the same type of ergometer used in this study. All six of the remaining subjects kept in good physical condition by exercising, running, or participating in competitive sports at least three times per week.

The original test work schedule was set at 30 min for each workload with no rest interval between workloads. This schedule was modified to include a 10-min rest between workloads when the older firefighters indicated that their "real world" workload was broken into 30-min work and 10-min rest time periods because of the current air supply limitations in the self-contained breathing apparatus. The workloads performed in this evaluation, set at ~25% and 50% of the subject's expected maximum oxygen consumption, were expected to be maintained for periods in excess of 1 hr (*35*), even at ambient temperatures of 41 °C, as long as they wore moisture-permeable clothing. Although the subjects were in good physical condition, two of the older firefighters had difficulty completing the full 100-W workload.

5.3 Respiratory/Exercise Tests

The oxygen concentration within the face piece decreased in four resting subjects while the blower was off. Simultaneously, the CO_2 concentration did not rise in the face piece. When each of these subjects adjusted the hood straps (without prompting) to tighten the nosecup against the face, the oxygen concentration rose in the face piece. This is because the only source of incoming filtered air through a properly sealed FIRM is from the blower hose, whether the blower is on or off. With the nosecup loosely fitting the face in an ambient pressure hood, normal breathing allows the face piece air into the nosecup through both the inhalation valves and, possibly, the less-than-adequate nosecup seal against that face. When the subject exhaled, the pressure within the nosecup was elevated, forcing the large in-turned peripheral seal to press back against the face and the inhalation valves to close against their valve seats. This air pathway's closing back into the face piece prevented any increase of CO_2 within that area and, at the same time, forced the exhaled CO_2 out of the nosecup through the exhalation valve. Because the internal temperature within the impermeable hood continued to rise while the blower was off, the humidity within the hood also rose from the subject sweating sensibly as well as insensibly. A functional pressure relief valve prevented the buildup of total ambient pressure in the hood. The partial pressure of this added water vapor in the hood reduced the concentration of the other enclosed gaseous constituents, thus reducing the inhaled oxygen concentration.

With the hood straps loose, ordinarily inhaling a small volume of air with each breath at rest did not cause the large internal hood to pulsate (i.e., rhythmically decrease and increase internal volume). Therefore, the oxygen concentration fell when more insensible sweat-water vapor entered the space within the hood. When the straps were tightened, however, breathing the same volume of air from this reduced-volume hood elevated the face piece oxygen concentration in two ways. The volume of humidified air breathed from the hood did not let the water vapor in the hood space increase sufficiently to lower the concentration of the incoming ambient oxygen. The pulsating characteristic of the reduced volume hood also forced some of the elevated water vapor air out of the exhalation valve at the back of the hood to maintain ambient pressure. This pulsating action, caused by breathing at rest with a properly tightened hood strap pushing the nosecup against the face, accounts for the breathing pulsation pattern observed in the subjects.

This same activity accounts for the increase in CO_2 concentration within the hood at rest with the blower off; an increased workload causes the decreased CO_2 concentration under the same conditions. At a high breathing rate through a nosecup held in place with properly adjusted hood straps, the air circulation within the hood changed too rapidly for CO_2 to build up to any significant extent. At rest with shallow breathing, however, the nosecup did not build up sufficient pressure during exhalation to force the inhalation valves against their seats. This permitted CO_2 to flow back into the hood. This phenomenon of the inhalation valves not closing in the presence of shallow breathing was observed in several subjects and was demonstrated to the FIRM manufacturer while he was witnessing this evaluation; when this was brought up several weeks later, he claimed to have corrected the stiffness of the inhalation valves.

As a subject speaks, the exhaled air passes through the exhalation valve. If this valve is stiff (i.e., has a high resistance to move when air flows against it), pressure will usually build up in the nosecup, also closing the inhalation valves. If the masked speaker talks rapidly, however, this exhaled air will flow rapidly through the mask. This can cause weak inhalation valves to crack open from the "Bernoulli Effect" (i.e., increased axial flow reduces lateral pressure, causing the valves to be lifted from their seats). By speaking quietly and slowly, the pressure in the nosecup will not build up; thus, weak inhalation valves will have a tendency to crack open due to lack of pressure holding them against their valve seats. This is believed to be the cause of the CO_2 elevation in the face piece of the subject who talked rapidly, but it was not observed when other nontalking subjects wore the same mask.

The rate of CO_2 diffusion through the skin enclosed within the FIRM is too slow to allow any significant concentration of that gas to accumulate in the presence of the expulsion phenomena previously described. While CO_2 can diffuse down its concentration gradient from within the body to the external environment, the body surface area enclosed within the hood, and the diffusion coefficient through skin, do not give this source of CO_2 in the FIRM very much credence. Even though the trapped heat in the hood increases the blood circulation in the enclosed skin and elevates the diffusion rate, the body has too many other methods of removing CO_2 more easily before it can build up to a physiologically significant problem within the FIRM. Air circulating between the skin and normal clothing will routinely show a CO_2 concentration of ~1%, depending on the porosity of the clothing, exercise level of the subject, ambient temperature, and wind velocity.

NIOSH indicated that they measured ~7% CO_2 in the FIRM when they tested the mask with a loose nosecup on a head form in their breathing simulator. Based on the human subject testing of the FIRM in our physiological evaluation, it must be assumed that the nosecup almost completely lost contact with the head form in their simulator. If the nosecup were not present within the hood, the hood volume would be the equivalent of an expanded respiratory physiological dead space. The exhaled CO_2 would rise in the hood because the hood volume would be greater than the breathing tidal volume. Hood concentrations of 6%–7% would be likely in the 20-min time frame over which they tested. The nosecup of the FIRM has too wide a flange on the in-turned peripheral seal to allow the nosecup to separate from the face completely, even when the straps are loose. The FIRM strap design forces the nosecup against the face as a pivot for the face piece. If the strap is loose, the wearer will automatically know about it and readjust the strap to make the seal comfortable, improve vision, etc. The FIRM is unique in this manner because the strap design of conventional respirators produces ambient environmental protective tightness by forcing the mask peripheral seal against the face rather than the nosecup. In a conventional mask design, the mask nosecup will possibly not even touch the face to produce a good reduced physiological dead space, thus raising CO_2 in the inhaled air.

When the blower was working to circulate air through the hood, there was no significant increase in air temperature within the hood. If the blower were not operational for any reason, however,

the temperature within the hood would increase depending on the level of exercise exerted. This evaluation was conducted in a neutral ambient temperature environment of 23 °C. In a higher ambient temperature, the heat further accumulated in the hood when the blower failed or was shut off. As the heat rises and the subject begins to sweat, the humidity also rises and possibly condenses on the inside of the face piece. This condensation should not fog the face piece to the extent that visibility would be lost. The diamond-hard coating on the inside of the lens will cause any condensation to form large droplets of water, rather than a fog, and run off of the face piece. This situation, as described, was observed during this evaluation when water droplets formed on the face piece of several subjects as they exercised at the 100-W workload. No face piece fogging was observed during the testing. One subject was observed to have minor fogging on the edge of his corrective lenses, but not on the FIRM face piece.

With each subject serving as his own unmasked control, minimal additional physiological burden was imposed on the subject by wearing the FIRM. The average heart rate wearing the FIRM was within six heartbeats/min of the corresponding control value when the mask was not worn. This heart rate differential, in most of the cases reported in the literature, is within the limitations and variability of the data collection method for that parameter. Even with the blower off at the 50-W workload, the average heart rate/5-min interval was almost identical with the heart rate observed with the blower on condition.

5.4 Vision Tests

Subjects who ordinarily used corrective lenses in their regular work activity wore their lenses under the FIRM. They had no difficulty in donning the mask; spreading their hands in the neck dam opening easily allowed them to clear the glasses as they donned the mask. Because the hands could not be placed in the same position in the neck dam opening when doffing the FIRM, the glasses were usually displaced and knocked off into the mask without damaging either the lenses or the interior surface of the face piece.

Several different tests were used to measure the same visual parameters. This approach was deliberate because it has been the experience of the senior author that slight changes in the lenses of masks can cause subtle, but important deficiencies in visual performance in the masked condition. For example, a person may be able to pass the Ishihara color chart test when masked, but that same masked subject may not be able to identify the white letters on a faded red "exit" sign. If that same masked subject passes the Farnsworth-Munsell color cap test, he will be able to distinguish the faded exit sign. The static acuity tests covered letters, numbers, and signs, to verify that each of those areas could be clearly identified. Depth perception was evaluated at infinite distance (Howard-Dolman test) as well as up close with the Frisby and Lang Stereo tests. Depth perception is a critical parameter. Infinite depth perception is needed for judging distance and safety conditions; close up depth perception is required for evaluating evidence on site and reading three-dimensional surfaces close up.

There was essentially no change in static visual acuity wearing the FIRM, compared to the same subject's unmasked control. This is very important because it was thought that the neck dam would constrict the flow of blood to the head, causing a decrease in visual acuity. This thin, one-size-fits-all neck dam did not have the same restricting effect observed by Langan and Watkins (*26*) when men wore shirt collars one size too small for the circumference of their necks. The neck seal opening in the FIRM appears to cover the full range of anthropometric sizes, without interfering with visual acuity. Subjects who showed a loss in visual acuity had essentially the same overlapping range of neck circumferences as those who showed an improvement in visual acuity wearing the FIRM. Corrective eyewear did not affect visual acuity, either through the presence of a second lens in the visual pathway or from any pressure of the face piece against the corrective lenses. One subject did comment that the nosecup caused his glasses to ride higher on his face than normal because they sat on the exterior surface of the nosecup. When he wore the glasses between the skin and nosecup, he was not able to get a good nosecup seal against the face, and CO_2 leaked into the face piece.

Contrast sensitivity is a realistic assessment of how we see large faint objects around us. In normal operations, where the FIRM is to be used, the environment may be darkened by low light levels, haze resulting from smoke, chemical clouds or dust, or confined spaces with intertwining components. The wearer must be able to distinguish objects in this situation. The Pelli-Robson contrast sensitivity test provided a standardized method for evaluating this parameter. There was essentially no difference between the masked and unmasked ability to distinguish various levels of contrast.

The FIRM slightly reduced the binocular peripheral visual field in the left and right lower quadrants when compared to normal visual peripheral fields (*36, 37*). This decrease is due to the presence of the sharp fold molded into the mask in these regions. The total binocular visual field of the FIRM is ~97% of the unmasked condition. This is better than most military masks, as well as most commercial civilian industrial masks. It is better than the normal peripheral field of view when a subject wears corrective lenses. The forward focusing lateral peripheral fields of the mask were 90°, the limit of the Goldman perimeter as it is normally configured. Because of the wide face piece and preliminary testing by the manufacturer, the FIRM peripheral fields might actually be larger when the subjects rotated their eyes in an ipselateral direction without moving their heads. This evaluation was accomplished by having the subject in the normal position at the Goldman perimeter, but having him focus at a point 45° to either side of directly forward of the FIRM. Even with this test modification, the edge of the FIRM was the 90° limiting factor in peripheral vision.

5.5 Acoustic Tests

The acoustical test matrix was designed to assess the communication characteristics of the FIRM in its anticipated operational modes: discussions prior to entering a contaminated area between unmasked and masked (with and without a blower on) personnel, between masked personnel

with blowers on, and between personnel when the blowers were off. To create a comparative evaluation environment, all the testing was done in a quiet open field of at least six acres to eliminate reverberation from nearby surfaces.

Both speech and hearing were very good when people communicated with their masks on and with their blowers off. When communication was between masked people with their blowers on, mixed results were obtained. When a masked person was talking with his blower on, the listener (unmasked or masked with the blower off) was able to hear speech with very good intelligibility. But if the situation was reversed, the masked listener, whose blower was on, had poor intelligibility of what was being said, which can be attributed to a manufacturing change in the FIRM. Listening intelligibility in the original FIRM prototypes was excellent when it contained welded seams where the external strap loops were attached to the hood. To meet the requirement to have the FIRM flexible at –30 °C, a different agent-resistant material was substituted to make the hood, so the strap loops had to be stitched to the hood. To prevent leakage through the stitching, luting tape was bonded to the interior surface of the hood directly over the stitches. This luting tape at the top and bottom of the strap-loop seams formed a channel from the air inlet on the face piece to the ear. Turbulent inlet air flowing through this channel partially distorted the sounds and lowered the intelligibility level for the listener. In the former condition, where a person spoke from the same mask, no changes were made, and speech intelligibility remained very good to excellent.

An analysis of the monosyllabic words missed did not show any trends in specific sound difficulty. All 50 words were missed at least once by the six subjects during this series of acoustical tests. No test for skin sensitivity was done as part of this test. However, based on over 100 subjects wearing the FIRM during the tests reported in this study and in field trials (some up to 8 hr in length on multiple occasions), no evidence of allergic reaction was found for up to seven days after the test/trials.

6. Conclusions

The FIRM is a unique, one-size-fits-all powered air purifying respirator that will easily meet the requirements established in 1996 by personnel responding to chemical/biological emergency domestic preparedness/terrorist incidents.

The mask is lightweight and comfortable to wear for long periods (12 hr) and is easy to don and doff rapidly, even over corrective lenses. Normal corrective lenses can be worn under the mask—no special glasses are needed.

The soft, pliable neck dam provides an effective, comfortable seal on the neck rather than the face. This configuration provides protection for a wide range of head and neck sizes, eliminating the need for multiple mask sizes. It also eliminates problems of potential respirator leakage due

to beards, mustaches, and long hair, irregular facial features, prescription eyewear, etc., that have disqualified mask use in past situations.

The wide, transparent face piece provides near nonmasked-quality visual capability and minimizes the claustrophobic feeling in personnel who seldom wear a mask. Wearing the mask, visual acuity, color acuity, depth perception, and contrast sensitivity were essentially the same as nonmasked control values in the same subject. The lateral visual peripheral field extended to only 90° on each side of the face, better than most military and industrial masks used today. There was a slight degradation of the full lens utilization due to a molded fold in the face piece in the left and right lower lateral quadrants. Even with this decrease, the subjects had better downward and sideward vision than they did with most other masks.

The mask provided adequate filtered ventilation to perform sustained heavy workloads. At a workload of 100 W maintained for 30 min, the mask showed only slight pulsation with each breath in some of the subjects; this indicated that they were not overbreathing the blower system. The oxygen concentration within the FIRM did not drop significantly to hypoxic levels with the blower off during both rest and exercise. It remained at or near ambient levels during rest and exercise with the blower on. With the blower off, the average oxygen concentration fell to ~20.2%.

The FIRM did not accumulate rebreatheable CO_2 in the face piece during normal operation, when the blower was off, or when the nosecup was not tight against the face. CO_2 concentrations within the hood remained at external ambient levels during both rest and exercise with the blower on.

When the blower was turned off or the nosecup was loose, CO_2 rose to an average of 0.29% for the 20-min test period. This would allow ample time for anyone in a contaminated area to reach safety when a blower fails or the battery is discharged. The preliminary finding of a CO_2 concentration of up to 7% inside the hood, over a 20-min period with the blower off (observed by NIOSH using a breathing simulator on this mask) was not detected when human subjects wore the FIRM.

Subjects wearing the FIRM easily drank 330 mL of water when they connected the mask's drink tube end fitting to the threads of a commercially available soda/water bottle. The drink tube on the FIRM is unequaled in industrial masks; the ability to connect to commercially available water/soda bottles is not possible with military masks.

Hearing is slightly degraded due to the luting straps inside the hood, which channels the air from the blower directly past the tragus on its way to the posterior exhalation valve.

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